Declaration under 37CFR 1.132

USA Patent Application 09/857,611

I Gregor Bruce Yeo Christie, a co-inventor of the invention defined in USA patent application 09/857611 hereby declare that:

1. I have reviewed and understand the contents of the examiners report.
2. I have read and believe I understand US Patent Nos. 5322866 [Mayer] and 5363777 [Tomka]
3. There have been many attempts to formulate useful starch based biodegradable polymers, but the acceptance has been limited because the cost of the biodegradable polymers has not been comparable to the costs of the non biodegradable polymers.
4. Other difficulties encountered with starch polymers are processing difficulties caused by incompatibility between the starch components and the blended polymers. Because of water content in the starch, foaming of the mixture in the extruder can occur. Also the starch cakes on the inside of the extruder and creates a cleaning difficulty.
5. In formulating a polymer for a particular application not only must the desirable properties be produced but the processability of the formulation and the cost of the formulation must also be acceptable. It is often the case that in overcoming one problem such as processability that desirable properties in the final polymer are compromised. In addition even if processability and properties are acceptable the costs are not price competitive with the non biodegradable polymer.
6. Thus to develop a suitable biodegradable formulation for a particular application a substitution of a component or a change in proportions of a component can make a significant difference in terms of processability, functional performance and/or price in an unpredictable way. The usual practice when developing a starch/water/ synthetic polymer system is to produce a large number of samples varying in concentration, ingredients, and processing conditions and then measure the mechanical properties of the samples. In my experience, contrary to the position outlined by the USPTO, there is no predictable out come from changing polymer types particularly when changing from water insoluble to water soluble polymer components.

7. This invention provides formulations containing
   a) 8 to 80% of a starch modified to include an hydroxyalkyl C_{2-6} group or modified by reaction with an anhydride of a carboxylic acid
   b) 4 to 11 % of a water soluble polymer selected from polyvinylacetate and polyvinyl alcohol
   c) up to 12% added water
   d) 0 to 10% of a polyol plasticiser
   e) 0.1 to 1.5% of a C_{12-22} fatty acid or salt
   f) the balance being a natural starch
8. This formulation was developed from extensive research to find an optimum mix that gave satisfactory properties and processability at a cost that was comparable to that of currently used polymers. The fast biodegradability of the blends is dependent on both the starch and the other polymer component being water soluble. The major reduction in cost was achieved by reducing the amount of polymer in component b). Cost is also reduced by reducing the amount of non water plasticizer to below 10%.
9. This formulation allows the extrusion processing to operate without caking of the extruder and without the need to vent the die. The polymers are blended for processing to form a melt at relative low temperatures of 130 °C to 160 °C. The die temperatures for the process can be maintained within the range of 85 °C to 105 °C which is much lower than was possible with prior art formulations. Operating at lower die temperatures reduces the need for venting and improves the performance characteristics of the polymer blend. These processing characteristics are derived from the combination of modified starch, natural starch and lower proportions of the water soluble non starch polymer as well as the inclusion of water as the essential plasticizer and a polyol as an **optional** additional plasticizer.
10. Mayer discloses forming a blend of raw starch and 20 to 80% polyvinyl alcohol or ethylene vinyl alcohol and talc and combining that with a mixture of water and 10 to 20 % of glycerol to produce blown films. The minimum quantity of polymer other than starch is greater than the maximum required in the formula given in paragraph 7 above. **The minimum amount of glycerol in Mayer is above the maximum amount of polyol plasticiser required in the formula of thi inv ntion.** In fact the use of a plasticizer in addition to

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water is OPTIONAL in the present invention. The processing requirements disclosed in Mayer use a minimum die temperature of 110 °C (see examples1) and 3) whereas the formulation of my invention allows processing at die temperatures below 105 °C.

11. Tomka discloses a high temperature process for processing starch. The starch material used may include chemically modified starch. An important requirement is that **no water is added to the starch** and Tomka uses 10 to 35% of a plasticizer (which may be a polyol). Tomka processes the starch at temperatures from 150 °C to 300 °C under conditions that have no water. As pointed out in column 12, Tomka eliminates foaming in the extruder by controlling water content and thus, **avoids added water.** There is no suggestion in Tomka as to the possibility of using chemically modified starches or in the presence of added water.

12. In paragraph 6 of the office action the examiner asserts that it would be obvious to combine the disclosure of Tomka that chemically modified starches could be used with the disclosure of Mayer. However a skilled polymer chemist would not combine these two disclosures and even if such a skilled person were to combine these two disclosures, the present invention would not be produced. Namely, Tomka clearly states that water is to be eliminated and not added whereas Mayer does allow for the addition of water. Neither reference teaches that the formulations could be processed at lower temperatures and be used in extruders with die temperatures in the range of 85 to 105 °C. Also neither references teach the use of a modified starch could allow the amount of non starch polymer to be reduced and thus reduce the cost of the formulations. Further neither reference teaches that the non water plasticizer can be reduced below 10% or not even be included at all.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U. S. C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Gregor Bruc Yeo Christi

15th day of July 2003

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